

REMARKS

Claims 1-6, 9-11, 21-32, 37 and 38 are pending in this application. Claims 1, 21 and 38 have been amended. Support for the amendments to claims 1 and 21 may be found in paragraphs 7, 22, 23 of U.S. Publication No. 2007/0045126. No new matter has been added. Thus, claims 1-6, 9-11, 21-32, 37 and 38 remain pending after entry of this Amendment. Reconsideration of the claims is respectfully requested.

35 U.S.C. § 112 Rejections

As suggested, claim 38 has been amended to change its dependency from claim 1 to claim 21. See page 2 of the Office Action. Thus, the 35 U.S.C. § 112, second paragraph, rejection should be withdrawn.

Claims 38 and 39 were rejected under 35 U.S.C. § 112, first paragraph. See page 3 of the Office Action. Specifically, the Office Action stated that “[t]hese claims recite the limitations that only one enzyme is present, yet there is no support in the specification for this claim. The specification teaches the presence of “an enzyme”, but in the interpretation of the examiner, this does not limit to only one enzyme necessarily as it doesn’t preclude the use of more than one enzyme.” The Applicants respectfully disagree that claims 38 and 39 are not supported in the specification. In addition to the teaching of the presence of an enzyme, the present application discloses several examples of reagent mixtures that include exactly one reagent. For example, Formulations 1-3 in the present invention include a reagent mixture with only one enzyme (PQQ-GDH). See paragraph 57 of the present invention. Thus, the 35 U.S.C. § 112, first paragraph, rejection should be withdrawn.

35 U.S.C. § § 102 / 103 Claim Rejections

Independent Claim 1

Claim 1 recites a working electrode, a counter electrode, a mediator, “the oxidizable species being different than the mediator species and having different redox potentials” and “said mixture being located as a single layer on a surface of at least a

portion of the working electrode and the counter electrode prior to the introduction of the test sample.” The present invention is advantageous because “[s]ince the internal reference concentration is fixed, the calibration scope of the sensor will only depend on the sensor response for glucose while the intercept will depend on the added amount of the internal reference. In [o]ther words, the internal reference will only offset the intercept and will not change the calibration scope.” Page 4, lines 9-13 of the patent application.

The applied reference of U.S. Patent No. 6,033,866 to Guo (“Guo”) does not disclose, teach or suggest “said mixture being located as a single layer on a surface of at least one of the working electrode and the counter electrode prior to the introduction of the test sample” as recited in claim 1.

Rather, Guo discloses a glucose biosensor 10 that is based on a two mediator – two enzyme redox system. Col. 2, lines 3-5. Guo discloses a face-to-face configuration of its electrodes in which the first redox mediator is contained in the conductive layer of the sensing electrode and the second redox mediator is contained in the reagent strip located between the electrodes. Col. 2, lines 10-16. In addition to the second redox mediator system, the reagent strip of Guo further includes two enzymes – glucose oxidase and horseradish peroxidase. Col. 2, lines 31-34.

As shown in FIG. 1D of Guo, the biosensor 10 has multiple layers including sensing electrode 20, reagent strip 16, whole blood separating membrane 38 and reference electrode 30. There is no disclosure, let alone a teaching or suggestion that the claimed mixture can be located on a surface of as a single layer with a portion located on the working and counter electrodes. The biosensor 10 of Guo is more complex using its multiple layers, multiple reagents and multiple mediators and does not offer the simplicity of the claimed test sensor especially in its manufacturability. In fact, Guo appears to teach away from less complicated test sensors (e.g., sensors using a single mediator) by the following passage:

Although amperometric sensors using a single mediator can be used to assay glucose, none really provides the combination of a wide response range, rapid response, a high degree of accuracy and precision over a wide response range and high sensitivity so that even relatively low concentrations of glucose such as found in urine could be assayed.

In response, the Office Action in discussing Guo mentions that reagent layer 16 “comprising an enzyme and second redox compound wherein the mediators or redox compounds can be found as mixtures (c. 6, l. 28-42)” and the “mediators and internal reference are taught in column 6, lines 28-42 to be any number of combinations which inherently will nearly all have different redox potentials.” See page 4 of the Office Action. However, as acknowledged in the Office Action, the reagent layer 16 is not directly on top of either electrode, let alone on the surfaces of both the working and counter electrodes as recited in amended claim 1. See *id.*

Therefore, claim 1 is not anticipated by or rendered obvious over Guo. Thus, claim 1 should be in a condition for allowance.

Dependent Claims 2-6, 9-11 and 37

To address further deficiencies in Guo, the Office Action has applied additional references (U.S. Patent No. 5,520,786 to Bloczynski (“Bloczynski”) and U.S. Publication No. 2004/0245121 to Nagakawa (“Nagakawa”) to selected claims. However, neither Bloczynski nor Nagakawa addresses the above noted deficiencies in Guo. Thus, dependent claims 2-6, 9-11 and 37 are not anticipated by or rendered obvious over Guo, Bloczynski, Nagakawa or any combination thereof for at least the reasons discussed above in claim 1.

Therefore, claims 2-6, 9-11 and 37 should be in a condition for allowance.

Independent Claim 21

Claim 21 recites a method of forming and placing a reagent mixture and includes, *inter alia*, “forming a batch of reagent mixture by adding an enzyme, adding a mediator and adding an oxidizable species, the added oxidizable species being added separately from the mediator” and “after forming the reagent mixture, placing the reagent mixture at least partially on a surface of the working electrode and the counter electrode of the biosensor prior to the introduction of the fluid sample.”

As discussed above in detail with respect to claim 1, Guo does not disclose, teach or suggest “after forming the reagent mixture, placing the reagent mixture at least partially on a surface of the working electrode and the counter electrode of the biosensor

prior to the introduction of the fluid sample.” This is acknowledged in the Office Action where the reagent layer 16 of Guo is not directly on top of either electrode, let alone on the surfaces of both the working and counter electrodes as recited in amended claim 21. See page 5 of the Office Action.

The Office Action discusses the term batch as follows: “The term batch is interpreted to mean that the pieces are brought together on the sensor wherein the batch is the necessary pieces of one sensor for example. Moreover, since each tangible piece is present discretely they are inherently added separately or in batch.” Page 5 of the Office Action.

The term “batch” is defined as a “quantity required for or produced as the result of one operation”. See Exhibit A (American Heritage Dictionary, 4th edition). The term batch is mentioned in the following passage of the present application as follows and is consistent with the above definition:

Most of the commercially available disposable biosensors used for monitoring blood glucose require the deposition/printing of a mixture of an enzyme and a mediator with some binding agent. For the application of glucose measurement, the mediator is in the oxidized form of a redox couple. Depending on the redox couple, the mediator can be a very strong oxidant, such as ferricyanide, thereby chemically oxidizing the functional groups after mixing with the enzyme and the binding agent. Subsequently, a small amount of the reduced mediator is formed as impurity in the reagent in the processes of ink mixing, storage and printing. Thus, the end result of mixing and printing the reagent ink is the generation of the reduced form of the redox couple, giving rise to the background current. The formation of this reduced form of the mediator and thus the background current may vary from batch to batch.

Paragraph 38 of the U.S. Publication No. 2007/0045126.

U.S. Publication No. 2001/0052470 to Hodges (“Hodges”) does not disclose, teach or suggest “forming a batch of reagent mixture by adding an enzyme, adding a mediator and adding an oxidizable species, the added oxidizable species being added separately from the mediator”.

Rather, Hodges discloses using a mediator (ferricyanide) that reacts and forms a product ferrocyanide. Paragraph 9 of Hodges. Hodges discloses that after the reaction is complete, the concentration of ferrocyanide indicates the initial concentration of glucose.

Id. This is done after the introduction of a fluid sample. Thus, Hodges does not disclose, teach or suggest at the time of forming the claimed batch by “adding an enzyme, adding a mediator and adding an oxidizable species.” Even if there were a small impurity of ferrocyanide in the mediator (ferricyanide) such as discussed above in Paragraph 38 of U.S. Publication No. 2007/0045126 or paragraph 9 of Hodges, the forming of the claimed batch recites that “the added oxidizable species [is] added separately from the mediator”. Such an impurity of ferrocyanide, if it exists in the Hodges process, would not be added separately from the mediator. It is also noted that over time, some of the ferricyanide may convert to ferrocyanide prior to the introduction of the sample, which can add to the background current discussed above in paragraph 38 of U.S. Publication No. 2007/0045126. This has nothing to do with the formation of the claimed batch that is placed on at least partially on a surface of the working electrode and the counter electrode of the biosensor prior to the introduction of the fluid sample.

The Office Action points to the passages at paragraph 69 and 70 of Hodges. See page 6 of the Office Action. These paragraphs are unclear and confusing. Specifically, Hodges discloses printing chemicals for use in the cell onto the palladium surface of the electrode. Paragraph 70 of Hodges. Hodges continues by providing an example of the same: “a solution containing 0.2 molar potassium ferricyanide and 1% by weight of glucose oxidase dehydrogenase may be printed on to the palladium surface.” *Id.* Hodges continues by stating:

Desirably, the chemicals are printed only in the areas which will form a wall of the cell and for preference the chemicals are printed on the surface by means of an ink jet printer. In this manner, the deposition of chemicals may be precisely controlled. If desired, chemicals which are desirably separated until required for use may be printed respectively on the first and second electrodes. For example, a GOD/ferrocyanide composition can be printed on one electrode and a buffer on the other. Although it is highly preferred to apply the chemicals to the electrodes prior to assembly into a cell, chemicals may also be introduced into the cell as a solution after step 6 or step 8 by pipette in the traditional manner and the solvent subsequently is removed by evaporation or drying.

Id. (emphasis added). A GOD/ferrocyanide composition, however, is not printed on the electrode. This is believed to be a typographical error and goes against all of the teachings of Hodges. Specifically, in addition to paragraph 70, the term “ferrocyanide” is

used at paragraphs 7-9 and 82 of Hodges. In Hodges, ferricyanide is the mediator and ferrocyanide is the product of the total reaction. Paragraph 9. Hodges states that “[i]deally there is initially no ferrocyanide, although in practice, there is often a small quantity.” *Id.* The term “ferrocyanide” is used in the phrase “GOD/ferrocyanide system” in paragraphs 7 and 82, but this refers to the system that measures the formed product ferrocyanide, not using ferrocyanide on the palladium surface.

Thus, Hodges does not disclose, teach or suggest “forming a batch of reagent mixture by adding an enzyme, adding a mediator and adding an oxidizable species, the added oxidizable species being added separately from the mediator”; and “after forming the reagent mixture, placing the reagent mixture at least partially on a surface of the working electrode and the counter electrode of the biosensor prior to the introduction of the fluid sample.”

Therefore, claim 21 is not anticipated by or rendered obvious over Guo or Hodges. Thus, claim 21 should be in a condition for allowance.

Dependent Claims 22-32 and 38

To address further deficiencies in Guo or Hodges, the Office Action has applied additional references (Bloczynski and Nagakawa) to selected claims. However, neither Bloczynski nor Nagakawa addresses the above noted deficiencies in Guo and Hodges. Thus, dependent claims 22-32 and 38 are not anticipated by or rendered obvious over Guo, Hodges, Bloczynski, Nagakawa or any combination thereof for at least the reasons discussed above in claim 21.

Therefore, claims 22-32 and 38 should be in a condition for allowance.

Independent Claim 39

To expedite prosecution, the Applicants will comment on the reference applied in connection with claim 1 with respect to added claim 39. Claim 39 recites a working electrode, a counter electrode, a mediator, “the oxidizable species being different than the mediator species and having different redox potentials” and “said mixture being located as a single layer on a surface of at least a portion of the working electrode prior to the introduction of the test sample.” For similar reasons as discussed above in claim 1, claim

39 is not anticipated by or rendered obvious over Guo. Thus, claim 39 should be in a condition for allowance.

Conclusion

The Applicants submit that the claims are in a condition for allowance and action toward that end is earnestly solicited. The Commissioner is authorized to deduct the two month extension fee from Nixon Peabody Deposit Account No. 50-4181, Order No. 247082-000168USPX. No other fees are believed to be due, but the Commissioner is authorized to deduct or credit any other fees (except the payment of the issue fee) from Nixon Peabody Deposit Account No. 50-4181, Order No. 247082-000168USPX.

Respectfully submitted,

Date: December 7, 2011

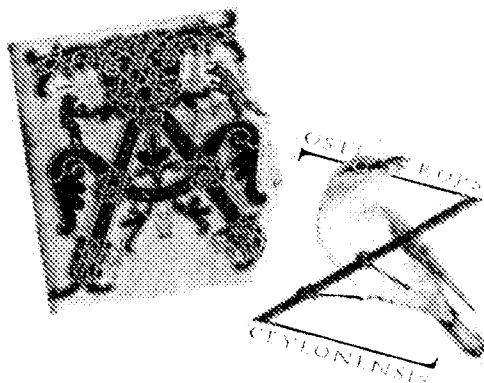
/John C. Gatz-Reg. No. 41,774/
John C. Gatz
Registration No. 41,774
NIXON PEABODY LLP
300 South Riverside Plaza, 16th Floor
Chicago, Illinois 60606
312-425-3900 - telephone
312-425-3909 - telefax

ATTORNEY FOR APPLICANTS

EXHIBIT A

The
**American
Heritage[®] Dictionary**
of the English Language

FOURTH EDITION



HOUGHTON MIFFLIN COMPANY
Boston New York

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1. English language—Dictionaries

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00-025369

Manufactured in the United States of America

basset hound *n.* A short-haired hunting dog of a breed originating in France and having a long body, short legs, and long drooping ears. [French, short, basset hound, diminutive of *basse*, fem. of *bas*, low. See *BASE*.]

bass fiddle (*bäs*) *n.* See **double bass**.

bass horn (*bäs*) *n.* 1. A large, valved, brass wind instrument with a low pitch; a tuba or sousaphone. 2. An instrument similar to the serpent but shaped like a bassoon, used primarily in military bands in the early 19th century.

bass (*bäs*) *n.* A plural of **basso**.

bassinet (*bäs'ä-nét', bäs'ä-nét'*) *n.* An oblong basketlike bed for an infant. [French, small basin, diminutive of *bassin*, basin, from Old French *bacin*. See **BASIN**.]

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[French, from Old French *bastillon*, from *bastille*, fortress. See **BASTILLE**.]

—**bas'tioned** *adj.*

bastnaesite (*bäst'na-sit'*) *n.* A yellowish to reddish-brown mineral, (Ce,La)CO₃(F,OH), that is a source of rare-earth elements, including gadolinium, samarium, and neodymium. [After *Bastnäs*, a mine in south-central Sweden.]

Bastogne (*bä-stön', bä-stön'yä*) A town of southeast Belgium near the Luxembourg border. It was a crucial point in the U.S. defensive line during the World War II Battle of the Bulge (December 1944–January 1945). Population: 11,386.

Ba'suto'land (*bä-sūō'tō-länd'*) See **Lesotho**.

bat (*bät*) *n.* 1. A stout wooden stick; a cudgel. 2. A blow, such as one delivered with a stick. 3. *Baseball* A rounded, often wooden club, wider and heavier at the hitting end and tapering at the handle, used to strike the ball. 4. *Sports* a. A club used in cricket, having a broad, flat-surfaced hitting end and a distinct, narrow handle. b. The racket used in various games, such as table tennis or racquets. *→ v. bat·ted, bat·ting, bats*

—*tr.* 1. To hit with or as if with a bat. 2. *Baseball* a. To cause (a run) to be scored while at bat: *batted the winning run in with a double.* b. To have (a certain percentage) as a batting average. 3. *Informal* To discuss or consider at length: *bat an idea around.* —*intr.* 1. *Baseball* a. To use a bat. b. To have a turn at bat. 2. *Slang* To wander about aimlessly. —**phrasal verb:** *bat out* *Informal* To produce in a hurried or informal manner: *batted out thank-you notes all morning.* —**idioms:** *at bat* *Sports* Taking one's turn to bat, as in baseball or cricket. *go to bat for* To give assistance to; defend. *off the bat* Without hesitation; immediately: *They responded right off the bat.* [Middle English, perhaps partly of Celtic origin and partly from Old French *batte*, pounding implement, flail (from *batre*, to beat; see **BAITER**).]

bat (*bät*) *n.* Any of various nocturnal flying mammals of the order Chiroptera, having membranous wings that extend from the forelimbs to the hind limbs or tail and anatomical adaptations for echolocation, by which they navigate and hunt prey. —**idiom:** *have bats in (one's) belfry* To behave in an eccentric, bizarre manner. [Alteration of Middle English *bakke*, of Scandinavian origin.]

bat (*bät*) *tr.v.* *bat·ted, bat·ting, bats* To wink or flutter: *bat one's eyelashes.* —**idiom:** *not bat an eye (or eyelash)* *Informal* To show no emotion; appear unaffected: *The reporter didn't bat an eyelash while reading the gruesome news.* [Probably a variant of **WAKE**.]

bat (*bät*) *n.* *Slang* A binge; a spree. [Probably from *butter*, spree.]

BAT *abbr.* Bachelor of Arts in Teaching

bat *abbr.* battalion

Bataan (*bä-tän', -tän'*) A peninsula of western Luzon, Philippines, between Manila Bay and the South China Sea. After an extended siege U.S. and Philippine World War II troops surrendered to the Japanese in April 1942. U.S. forces recaptured the peninsula in February 1945.

Ba'tan Islands (*bä-tän'*) The northernmost island group of the Philippines, separated from southern Taiwan by a narrow channel.

bat·ta·ta (*bä-tä'tä*) *n.* A type of sweet potato having somewhat dry, bland, yellowish to white flesh, used as a staple food in many tropical countries. Also called *boniato*, *canote*. [American Spanish, perhaps of Taino origin.]

Ba·ta·vian (*bä-tä've-ä*) See **Jakarta**.

bat·boy (*bät'boy'*) *n.* A boy who is employed by a baseball team to look after its equipment, especially the bats.

batch (*bäch*) *n.* 1. An amount produced at one baking: *a batch of cookies.* 2. A quantity required for or produced as the result of one operation: *made a batch of cookie dough; mixed a batch of cement.* 3. A group of persons or things: *a batch of tourists; a whole new batch of problems.* 4. *Computer Science* A set of data or jobs to be processed in a single program run. *→ tr.v. batched, batch·ing, batch·es* To assemble or process as a batch. [Middle English *bache*, probably from Old English **hæce*, from *hacan*, to bake.]

batch (*bäch*) *n.* & *v.* *Informal* Variant of **bach**.

bate (*bät*) *tr.v.* *bat·ed, bat·ing, bates* 1. To lessen the force or intensity of; moderate: *To his dying day he bated his breath a little when he told the story* (George Eliot). See **Usage Note** at **bait**. 2. To take away; subtract. [Middle English *baten*, short for *abaten*. See **ABATE**.]

bate also **bait** (*bät*) *intr.v.* *bat·ed, bat·ing, bates* also *bait·ed, bait·ing, baits* To flap the wings wildly or frantically. Used of a falcon. [Middle English *baten*, from Old French *batre*, to beat. See **BAITER**.]

♦ **ba·teau** also **bat·teau** (*bä-tō'*) *n., pl. -teaux* (*-toz'*) *Nautical* 1. *Canada & New England* A long, light, flatbottom boat with a sharply pointed bow and stern. 2. *South Atlantic & Gulf States* A small, light, flatbottom rowboat. [Canadian and Louisiana French, from French, boat, from Old French *batel*, from Old English *bāt*. See **bheid-** in Appendix I.]

bateau bridge *n.* See **pontoon bridge**.

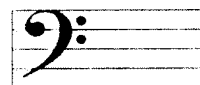
Bates (*bäts*), **Katherine Lee** 1859–1929. American educator and writer best known for her poem "America the Beautiful," written in 1893 and revised in 1904 and 1911.

Bates·ian mimicry (*bät'sē-ön*) *n.* A form of protective mimicry in which an unprotected species, especially of an insect, closely resembles an unpalatable or harmful species and therefore is similarly avoided by predators. [After Henry Walter Bates (1825–1892), British naturalist.]

Bate·son (*bät'son*), **William** 1861–1926. British biologist who was one of the founders of the science of genetics. He experimentally proved Gregor Mendel's theories on heredity and published the first English translation of Mendel's work in 1900.

BATF *abbr.* Bureau of Alcohol, Tobacco, and Firearms

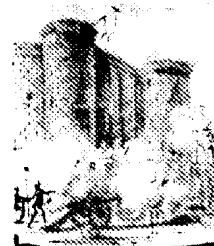
bat·fish (*bät'fish'*) *n., pl. batfish* or *-fish·es* Any of various marine



bass clef



basset hound



Bastille Day

detail from a print depicting the storming of the Bastille

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| ö pot | zh vision |
| o toe | a about, item |
| ö paw | ♦ regionalism |

Stress marks: / (primary), / (secondary), as in dictionary (dik'sha-när)